

***Remarks***

Reconsideration of this Application is respectfully requested.

Claims 1-39 are pending in this application, with claims 21 and 30 being the independent claims. Claims 1-20 have been withdrawn. Claims 21-34 are sought to be amended. New claims 35-39 are sought to be added. Support for these amendments may be found throughout the specification and claims as originally filed. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

***I. Rejection under 35 U.S.C. § 112, First Paragraph***

The Examiner has rejected claims 22-26 and 30-34 under 35 U.S.C. § 112, first paragraph, alleging that the claims are indefinite. (Office Action ("OA"), page 3). More specifically, the Examiner has asserted that "greater than about 95%," as recited in claim 22, does not delineate a clear lower limit to the claim. (OA, page 3). The Examiner has asserted that "less than about 5%," as recited in claim 23, does not define the range of values which correspond to the term "about." (OA, page 3). Similarly, the Examiner has rejected the phrase, "less than about 0.002  $\mu\text{g}$ ," asserting that the variance permitted by "about" is unclear because Applicants did not define the range of values that correspond to the term "about." (OA, page 3). Applicants respectfully traverse this rejection.

Solely to advance prosecution and not in acquiescence of the Examiner's rejection, the language objected to by the Examiner in claims 21-26 and 30-34 has been

deleted. The claims have been amended to define a minimum and maximum value for each recited range, or to recite specific numerical values. Applicants submit that the Amendment overcomes the outstanding rejection. Reconsideration and withdrawal of this rejection is respectfully requested.

**II. Rejection under 35 U.S.C. § 102(b)**

The Examiner has rejected claims 21-34 under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Published Application No. 2001/0034435 A1, to Nochumson *et al.* ("Nochumson *et al.*"). More specifically, the Examiner has asserted that on page 8, [0099] of the published application, Nochumson *et al.* teach plasmid DNA and pharmaceutical preparation with 95% plasmid DNA and less than 5% RNA, as recited in claims 21-23. (OA, page 6). Additionally, the Examiner asserted that Nochumson *et al.* teach plasmid DNA preparation with 0.05% of host DNA; less than 0.06% of protein; 0.1% protein (equivalent to 0.001 µg); and less than about 0.01 EU/µg, as recited in claims 24-26. (OA, page 7). With regard to claims 30-34, the Examiner asserted that page 8 [0099] of Nochumson *et al.* teaches plasmid DNA preparation with 95% plasmid DNA, less than 5% RNA, 0.05% host DNA, 0.2% host DNA, less than 0.06% protein, less than 0.001 µg of protein/µg of DNA product, and less than about 0.01 EU/µg, as recited in the claims. (OA, page 7). Applicants respectfully traverse this rejection.

Solely to advance prosecution, and not in acquiescence of the Examiner's rejection, claims 21-29 have been amended to recite a DNA product comprising from about 95% to about 100% circular plasmid DNA, wherein the DNA product contains from about 0.0001% to about 5% RNA; from about 0.00004 µg to about 0.002 µg host

DNA/ $\mu$ g DNA product; from about 0.00000001  $\mu$ g to about 0.001  $\mu$ g protein per  $\mu$ g DNA product; and from about 0.00001 to about 0.01 Endotoxin Units/ $\mu$ g DNA product. Claims 30-34 have been amended to recite a DNA product comprising from about 95% to about 100% by weight of circular plasmid DNA, wherein the DNA product contains amounts of host cell derived impurities that are undetectable by any one of a group consisting of: LAL assay, Southern blot assay, chromatography, Northern blot assay, and ethidium bromide agarose analysis. Nochumson *et al.* do not disclose a DNA product with the high levels of purity recited in claims 21-39. Accordingly, Nochumson *et al.* do not disclose the claimed invention and cannot anticipate the claims under  $\S$  102(b). Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

### ***Conclusion***

All of the stated grounds of objection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all currently outstanding rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in cursive script that reads "Laura Vogel". The signature is fluid and elegant, with the first letters of each word being capitalized and prominent.

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